

10/501412

PATENT Case No. ITR0037YP

DT11 Rec'd PCT/PTO 12 JUL 2004

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: De Tomassi, A. et al.

Serial No. To Be Assigned

Art Unit: \_\_\_\_\_

Filed: On Even Date Herewith

Examiner: \_\_\_\_\_

For: GB VIRUS B BASED REPLICONS AND REPLICON  
ENHANCED CELLSCommissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to the waiver by the Office of the requirement under 37 CFR 1.98 (a)(2)(i) dated July 11, 2003, if the filing date of this application is after June 30, 2003, copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

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MERCK &amp; CO., INC.

By \_\_\_\_\_

Date \_\_\_\_\_

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## INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☒ the attached information is filed within three months of the filing date of the captioned case.
- ☐ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action or Notice of Allowance. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ the undersigned certifies that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
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Respectfully submitted,



By: Sheldon O. Heber

Attorney \_\_\_\_\_ For Applicant(s)

Reg. No. 38,179

MERCK & CO., INC.

Patent Dept., RY60-30

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Date: July 12, 2004

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Substitute for form 1449B/PTO

# **INFORMATION DISCLOSURE**

## **STATEMENT BY APPLICANT**

(use as many sheets as necessary)

**COMPLIANCE KNOWN**

Application Number

**10/501412**

Filing Date

**DT11**

**Rec'd PCT/PTO 12 JUL 2004**

First Named Inventor

De Tomassi, A. et al.

Group Art Unit

Examiner Name

Attorney Docket Number

ITR0037YP

Sheet

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of

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### **NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Bartenschlager, R. et al. "Novel cell culture systems for the hepatitis C virus", Antiviral Research, 2001, Vol. 52, pp. 1-17
		Beames, B. et al. "Development of a Primary Tamarin Hepatocyte Culture System for GB Virus-B: a Surrogate Model for Hepatitis C Virus", Journal of Virology, 2000, Vol. 74, pp. 11764-11772
		Blight, K. et al. "Efficient Initiation of HCV RNA Replication in Cell Culture", Science, 2000, Vol. 290, pp. 1972-1974
		Bukh, J. et al. "Host Range Studies of GB Virus-B Hepatitis Agent, the Closest Relative of Hepatitis C Virus, in New World Monkeys and Chimpanzees", Journal of Medical Virology, 2001, Vol. 65, pp. 694-697
		Bukh, J. et al. "Toward a Surrogate Model for Hepatitis C Virus: An Infectious Molecular Clone of the GB Virus-B Hepatitis Agent", Virology, 1999, Vol. 262, pp. 470-478
		Butkiewicz, N. et al. "Virus-Specific Cofactor Requirement and Chimeric Hepatitis C Virus/GB Virus B Nonstructural Protein 3", Journal of Virology, 2000, Vol. 74, pp. 4291-4301
		De Tomassi, A. et al. "Cell Clones Selected from the Huh7 Human Hepatoma Cell Line Support Efficient Replication of a Subgenomic GB Virus B Replicon", Journal of Virology, 2002, Vol. 76, pp. 7736-7746
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		Grace, K. et al. "The 5' untranslated region of GB virus B shows functional similarity to the internal ribosome entry site of hepatitis C virus", Journal of General Virology, 1999, Vol. 80, pp. 2337-2341
		Guo, J. et al. "Effect of Alpha Interferon of the Hepatitis C Virus Replicon", Journal of Virology, 2001, Vol. 75, pp. 8516-8523
		Lohmann, V. et al. "Mutations in Hepatitis C Virus RNAs Conferring Cell Culture Adaptation", Journal of Virology, 2001, Vol. 75, pp. 1437-1449
		Lohmann, V. et al. "Replication of Subgenomic Hepatitis C Virus RNAs in a Hepatoma Cell Line", Science, 1999, Vol. 285, pp. 110-113
		Muerhoff, A. et al. "Genomic Organization of GB Viruses A and B: Two New Members of the <i>Flaviviridae</i> Associated with GB Agent Hepatitis", Journal of Virology, 1995, Vol. 69, pp. 5621-5630
		Ohba, K. et al. "Evolutionary relationship of hepatitis C, pesti-, flavi-, plantviruses, and newly discovered GB hepatitis agents", FEBS Letters, 1996, Vol. 378, pp. 232-234

Examiner Signature

Date Considered

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
 STATEMENT BY APPLICANT**

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**COMPLETELY KNOWN**

Application Number	10/501412
Filing Date	DT 11 Rec'd PCT/PTO 12 JUL 2004
First Named Inventor	De Tomassi, A. et al.
Group Art Unit	
Examiner Name	
Attorney Docket Number	ITR0037YP

Sheet 3 of 3

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Pietschmann, T. et al. "Characterization of Cell Lines Carrying Self-Replicating Hepatitis C Virus RNAs", Journal of Virology, 2001, Vol. 75, pp. 1252-1264
		Pizzuti, M. et al. "Replication and IRES-Dependent Translation Are Both Affected by Core Coding Sequences in Subgenomic GB Virus B Replicons" Journal of Virology, 2003, Vol. 77, pp. 7502-7509
		Rijnbrand, R. et al. "Mutational Analysis of the GB Virus B Internal Ribosome Entry Site", Journal of Virology, 2000, Vol. 74, pp. 773-783
		Rijnbrand, R. et al. "The influence of downstream protein-coding sequence on internal ribosome entry on hepatitis C virus and other flavivirus RNAs", RNA, 2001, Vol. 7, pp. 585-597
		Sbardellati, A. et al. "Generation of infectious and transmissible virions from a GB virus B full-length consensus clone in tamarins", Journal of General Virology, 2001, Vol. 82, pp. 2437-2448
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		Sbardellati, A. et al. "Processing of GB virus B non-structural proteins in cultured cells requires both NS3 protease and NS4A cofactor", Journal of General Virology, 2000, Vol. 81, pp. 2183-2188
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		Seipp, S. et al. "Hepatotropism of GB virus C (GBV-C): GBV-C replication in human hepatocytes and cells of human hepatoma cell lines", Journal of Hepatology, 1999, Vol. 30, pp. 570-579
		Simmonds, P. "The origin and evolution of hepatitis viruses in humans", Journal of General Virology, 2001, Vol. 82, pp. 693-712
		Simons, J. et al. "Identification of two flavivirus-like genomes in the GB hepatitis agent", Proc. Natl. Acad. Sci., USA, 1995, Vol. 92, pp. 3401-3405
		Traboni, C. et al. "The GB Viruses: A Comprehensive Survey", Recent Research Developments in Virology, 1999, Vol. 1, pp. 631-653, Part III (S.G. Pandalai Ed.), Transworld Research Network
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		Zhong, W. et al. "RNA-dependent RNA polymerase activity encoded by GB virus-B non-structural protein 5B", Journal of Viral Hepatitis, 2000, Vol. 7, pp. 335-342
		Accession No. AJ277947, March 1, 2002

Examiner  
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\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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